Application No.	Drug	Applicant
ANDA 077895	Ursodiol Capsules USP, 300 mg	Impax Laboratories, LLC, 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 078810	Oxaliplatin for Injection, 50 mg/vial and 100 mg/vial	Fresenius Kabi Oncology Plc., c/o Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 080420	Lidocaine Hydrochloride (HCl) Injection USP, 1%, 1.5%, and 2%.	Lyphomed, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160.
ANDA 080421	Procaine HCl Injection USP, 1% and 2%	Do.
ANDA 083083	Lidocaine HCl Injection USP, 1% and 2%	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101.
ANDA 083744	Lidocaine HCl Injection USP, 0.5%, 1%, 1.5%, and 2%	Tera Pharmaceuticals, Inc., 6920 Stanton Ave., Buena Park, CA 90621.
ANDA 083907	Lidocaine HCl With Epinephrine Injection USP	Do.
ANDA 084571	Lidocaine HCl Injection, 10 mg/20 mL and 10 mg/50 mL	Knoll Pharmaceuticals, 30 North Jefferson Rd., Whippany, NJ 07981.
ANDA 084572	Lidocaine HCl Injection, 20 mg/20 mL and 20 mg/50 mL	Do.
ANDA 084720	Lidocaine HCl and Epinephrine Injection USP, 2%; 0.01 mg/mL.	Naska Pharmacal Co., Inc., Riverview Rd., P.O. Box 898, Lincolnton, NC 28093.
ANDA 084732	Lidocaine HCl and Epinephrine Injection USP, 2%; 0.02 mg/mL.	Do.
ANDA 084947	Alphacaine (lidocaine) Ointment, 5%	Carlisle Laboratories, Inc., 404 Doughty Blvd., Inwood, NY 11696.
ANDA 085037	Lidocaine HCl Injection USP, 1% and 2%	Akorn, Inc., P.O. Box 1220, Decatur, IL 62525.
ANDA 085677	Cortisone Acetate Injectable Suspension USP, 25 mg/mL and 50 mg/mL.	Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043.
ANDA 088051	Thalitone (chlorthalidone) Tablets USP, 25 mg	Casper Pharma LLC, 2 Tower Center Blvd., Suite 1101C, East Brunswick, NJ 08816.
ANDA 089688	Lidocaine HCl Topical Solution USP, 4%	Paco Research, Corp., 1705 Oak St., Lakewood, NJ 08701.
ANDA 091212	Lansoprazole Delayed-Release Capsules USP, 15 mg and 30 mg.	Krka, tovarna zdravil, d.d., Novo mesto, c/o KRKA USA, LLC.
ANDA 091377	Vancomycin HCl for Injection USP, EQ 500 mg base/vial and EQ 1gram (g) base/vial.	Xellia Pharmaceuticals ApS, c/o Xellia Pharmaceuticals USA, LLC, 8841 Wadford Dr., Raleigh, NC 27616.
ANDA 206243	Vancomycin HCl for Injection USP, EQ 5 g base/vial and EQ 10 g base/vial (Pharmacy Bulk Package).	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 7, 2019. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on March 7, 2019, may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01129 Filed 2–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1987–D–0240 (formerly 87D–0315)]

Neomycin Sulfate for Prescription Compounding; Withdrawal of Approval of One Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 061579 for nonsterile neomycin sulfate powder for prescription compounding. The basis for the withdrawal is that the product is no longer considered safe as labeled due to clinical evidence that systemic exposure to neomycin sulfate can induce significant toxicity, including ototoxicity (manifested as sensorineural hearing loss), nephrotoxicity, and neuromuscular blockade. The holder of this ANDA has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of February 5, 2019.

FOR FURTHER INFORMATION CONTACT: Kate Greenwood, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6286, Silver Spring, MD 20993–0002, 240–402–1748.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 15, 1988, FDA published four documents arising out of the Agency's finding that systemic absorption of neomycin sulfate can induce significant toxicity, including ototoxicity (manifested as sensorineural hearing loss), nephrotoxicity, and neuromuscular blockade (see generally 53 FR 12644; 53 FR 12658; 53 FR 12662; and 53 FR 12664 (April 15, 1988)). Two of the four documents were issued under docket numbers FDA–1979–N–0220 and FDA–1987–D–0240 and related to nonsterile neomycin sulfate for prescription compounding.[1]

Under docket number FDA–1979–N–0220, FDA published a final rule amending the antibiotic drug

[1] These documents were originally assigned docket numbers 79N–0155, and 87D–0315. The numbers were changed to FDA–1979–N–0220 and FDA–1987–D–0240, respectively, as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008. The other two documents were issued under docket number FDA–1979–N–0256 (formerly 79N–0151) and related to neomycin sulfate in sterile vials for parenteral use.

regulations governing the certification of nonsterile neomycin sulfate powder for prescription compounding (53 FR 12644). Based on its evaluation of the written and oral comments received on the proposed rule (44 FR 44180 (July 27, 1979)), and based on other information, FDA concluded that there was a favorable risk:benefit profile for orally administered neomycin sulfate preparations as adjunctive therapy for preoperative suppression of intestinal bacteria and for the treatment of hepatic coma. However, consistent with the findings published in the proposed rule, FDA concluded in the final rule that the risks of adverse reactions from the use of the product for wound irrigation resulted in systemic absorption and a resultant risk of adverse reactions that significantly outweighed any demonstrated benefits. Accordingly, the final rule amended the antibiotic drug regulations by changing the product name from ''neomycin sulfate for prescription compounding'' to ''neomycin sulfate for compounding oral products'' and by requiring package insert labeling to provide information concerning the appropriate uses of the product and to warn about the risks associated with inappropriate use.

Under docket number FDA–1987–D–0240, FDA proposed to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) withdrawing approval of six antibiotic drug applications and abbreviated antibiotic drug applications (AADAs) [2] for nonsterile neomycin sulfate for prescription compounding products unless the application holders submitted supplemental applications providing for a product name and labeling consistent with the revised name and labeling requirements described in the newly amended antibiotic certification regulations (53 FR 12662).[3] In the document, FDA announced the availability of guideline labeling for nonsterile neomycin sulfate for prescription compounding products that manufacturers could adopt to ensure that their labeling would be consistent with the labeling required by the revised antibiotic certification regulations. The proposed order was based on clinical or other experience, tests, or other scientific data that showed nonsterile neomycin sulfate was unsafe for use except when named ''Neomycin Sulfate for Compounding Oral Products'' and used in accordance with package insert labeling that provides information concerning appropriate uses and that warns about risks associated with inappropriate use. Under section 505 and the regulations promulgated at 21 CFR parts 310 and 314, the holders of the applications were given the opportunity for a hearing to show why approval should not be withdrawn. One application holder, Pharma-Tek, Inc. (Pharma-Tek), requested a hearing to challenge FDA's proposal to withdraw approval of its application, AADA 61–579. On December 6, 1988, FDA announced the withdrawal of approval of five of the six applications for nonsterile neomycin sulfate for prescription compounding for which the holders had not requested a hearing (53 FR 49231). The AADA for neomycin sulfate for prescription compounding, AADA 61–579, held by Pharma-Tek, was not withdrawn at that time because of the sponsor's pending hearing request. Today, this application corresponds to ANDA 061579 held by X-Gen Pharmaceuticals, Inc. (X-Gen).

X-Gen informed FDA by letter dated October 9, 2015, that it was withdrawing the hearing request previously filed on behalf of its predecessor Pharma-Tek concerning ANDA 061579. X-Gen also informed FDA that it waived the opportunity for a hearing and, under 21 CFR 314.150(d), X-Gen permitted the Agency to withdraw approval of ANDA 061579 for neomycin sulfate for prescription compounding.

For the reasons discussed in the document published in the **Federal Register** on April 15, 1988, under docket number FDA–1987–D–0240, the Director of FDA's Center for Drug Evaluation and Research finds that ANDA 061579 was withdrawn from sale for safety and effectiveness reasons (21 CFR 314.161(c)). The Director, under section 505(e) of the FD&C Act and under authority delegated to her by the Commissioner, also finds that new evidence of clinical experience, not contained in ANDA 061579 and not available at the time the application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that nonsterile neomycin sulfate for prescription compounding is not shown to be safe for use under the conditions of use upon the basis of which the application was approved (21 U.S.C. 355(e)). Therefore, approval of ANDA 061579 is hereby withdrawn.

Under 21 CFR 314.161(e) and 314.162(a)(2), FDA will remove ANDA 061579 from the list of drug products with effective approvals published in FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations.''

Dated: January 23, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–01131 Filed 2–4–19; 8:45 am]

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[2] The terms ''antibiotic drug applications'' and ''abbreviated antibiotic drug applications'' are no longer used. AADAs approved under section 507 of the FD&C Act on or before November 20, 1997, are deemed to have been approved under section 505(j) of the FD&C Act.

[3] This proposed regulatory action was necessary because the antibiotic drug certification regulations did not apply to products with applications in which FDA had approved alternative labeling.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6702]

The Least Burdensome Provisions: Concept and Principles; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''The Least Burdensome Provisions: Concept and Principles.'' FDA utilizes a least burdensome approach to medical device regulation to eliminate unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for clearance and approval. This document describes the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on February 5, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are